IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-125 (LPS)
	)	
ARCHERDX, INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Natera, Inc. ("Natera"), for its First Amended Complaint against defendant ArcherDX, Inc. ("Archer"), hereby alleges as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action brought under 35 U.S.C. § 271 arising from Archer's infringement of Natera's United States Patent No. 10,538,814 ("the '814 patent"), United States Patent No. 10,557,172 ("the '172 patent"), United States Patent No. 10,590,482 ("the '482 patent"), and United States Patent No. 10,597,708 ("the '708 patent") (collectively, the "Asserted Patents"), by the manufacture, use, sale, and offer to sell of Archer's LiquidPlex (previously called Reveal ctDNA), Stratafide, Personalized Cancer Monitoring ("PCM"), ArcherMET, FusionPlex, and VariantPlex products, and any other oncology products that use the same technology as the previously mentioned products (collectively, the "Accused Products"). The Accused Products all use Archer's Anchored Multiplex PCR ("AMP") on nucleic acids. ArcherDX does not have freedom to operate its AMP products for minimal residual disease ("MRD") and personalized cancer monitoring. Natera brings this action to stop Archer's infringement of Natera's innovative, patented technology.

THE PARTIES

2. Plaintiff Natera is a corporation organized and existing under the laws of Delaware, with its principal place of business at 201 Industrial Road, San Carlos, California 94070.

3. Founded in 2004, Natera (f.k.a. Gene Security Network) is a pioneering molecular technology company with industry-leading healthcare diagnostics products. Natera is dedicated to improving disease management for oncology, reproductive health, and organ transplantation. For well over a decade, Natera has been researching and developing non-invasive methods for analyzing DNA in order to help patients and doctors manage diseases. These ongoing efforts have given rise to a number of novel and proprietary genetic testing services to assist with life-saving health management.

4. Since 2009, Natera has launched ten molecular tests, many of which are available through major health plans accounting for more than 140 million covered persons in the United States. Natera's own robust laboratory processes thousands of genetic tests per month.

5. Natera's pioneering and ongoing innovation is especially evident in the area of cell-free DNA ("cfDNA")-based testing. In the cfDNA field, Natera has developed unique and highly optimized cfDNA-based processes that can be used to test non-invasively for a range of conditions. Natera developed an industry-leading cfDNA test, Panorama, which showcases Natera's mastery of cfDNA in the field of non-invasive diagnostics. Natera is considered the industry leading test in this space, with over two million tests performed commercially and more than twenty-six peer-reviewed publications. Natera has also applied its cfDNA platform to the challenge of detecting and monitoring cancer.

6. In detecting and monitoring cancer, the use of minimally invasive, blood-based tests offers significant advantages over older methods, such as invasive tumor biopsy. But the significant technological challenge is that such blood-based testing requires the measurement of

very small amounts of relevant genetic material—circulating-tumor DNA ("ctDNA")—within a much larger blood sample. Natera's approach combines proprietary molecular biology and computational techniques to measure genomic variations in tiny amounts of DNA, representing a fundamental advance in molecular biology.

7. Natera has researched and developed cfDNA technology to provide patients and healthcare providers with tools for early, clinically meaningful detection and monitoring of cancer.

8. Natera's cfDNA platform is the product of well over a decade of hard work and investment of, on average, more than fifty million dollars per year in research and development. Natera has expended substantial resources researching and developing its technologies and establishing its reputation among physicians, insurers, and regulators as a company committed to sound science and consistently accurate, reliable results. This research, and the technological innovations resulting therefrom, are protected by a substantial patent portfolio, with over 200 patents issued or pending worldwide, including greater than 60 in the field of oncology.

9. Among these patented inventions are the Asserted Patents, which Archer infringes. Archer has used Natera's patented technology without permission and in violation of the patent laws.

10. Defendant Archer is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 2477 55th Street, Suite 202, Boulder, CO 80301.

11. Instead of developing its own science for its cancer detection and monitoring products, Archer has unlawfully used Natera's patented technology.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising under the Patent Act and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201-2202.

13. This Court has personal jurisdiction over Archer because Archer is a Delaware corporation.

14. This Court also has jurisdiction over Archer because, upon information and belief, Archer, directly or indirectly, uses, offers for sale, and/or sells the Accused Products throughout the United States, including in this judicial district.

15. This Court also has jurisdiction over Archer because Archer has availed itself of this forum, initiating civil actions in this jurisdiction including *ArcherDX, Inc. et al v. QIAGEN Sciences, LLC et al*, 18-1019-MN (D. Del. 2018).

16. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Archer is a Delaware corporation.

BACKGROUND

17. Since 2004, Natera has been a global leader in genetic testing, diagnostics, and DNA testing, including cfDNA testing. Natera's mission is to improve the management of disease worldwide and focuses on reproductive health, oncology, and organ transplantation. In pursuit of these goals, Natera has developed novel technologies to make significant and accurate clinical assessments from the miniscule amounts of cfDNA present in a single blood sample. These technologies include methods to manipulate cfDNA in unconventional ways in order to capture information about genetic variations in cfDNA and usefully transform that information for noninvasive testing.

18. Natera develops and commercializes innovative, non-traditional methods for manipulating and analyzing cfDNA, and offers a host of proprietary cfDNA genetic testing services to the public to assist patients and doctors to evaluate and track critical health concerns.

19. Since its founding, Natera has researched, developed, and released ten molecular tests with applications in prenatal diagnostics, cancer, and organ transplants, many of which are available through major health plans, or covered by Medicare or Medicaid, and therefore available to most patients in need of those tests. Natera's tests have helped more than two million people to date. Natera's robust laboratory now processes tens of thousands of tests per month in the United States and internationally, improving the ability of physicians to monitor and manage crucial health issues and patients to prosper around the world.

20. Building on these innovations, in 2017, Natera launched its cfDNA diagnostic test to detect and monitor cancer, called Signatera®. Signatera® is a personalized ctDNA surveillance tool that detects MRD when assessing disease recurrence or treatment response in solid tumors. Signatera® is designed to screen for multiple tumor-derived targets with each assay. It is optimized to detect extremely low quantities of ctDNA and provides early knowledge of disease recurrence with a >99.5% clinical test specificity.

21. MRD assessment has become a standard of care in the management of patients with hematological malignancies, but until recently it has not been possible in solid cancers due to technical limitations. Accurate MRD testing and molecular monitoring offers the potential for physicians to change or escalate treatment in patients who are MRD-positive, and to de-escalate or avoid unnecessary treatment in patients who are MRD-negative. It also holds potential as a surrogate endpoint in clinical trials.

22. Natera's technology has been validated in multiple clinical studies. In Cancer Research UK/University College London's Tracking Cancer Evolution through Therapy ("TRACERx"), Natera's technology was used for the multi-year monitoring of patient-specific single-nucleotide variants (SNVs) in plasma, to understand the evolution of cancer mutations over time, and to monitor patients for disease recurrence. Results from the first 100 early-stage lung cancer patients analyzed as part of the study were featured on the cover of the May 2017 issue of Nature and showed that an early prototype version of Signatera identified 43% more ctDNA-positive early-stage lung cancer cases than a generic lung cancer panel and demonstrated its potential to detect residual disease, measure treatment response, and identify recurrence up to 11 months earlier than the standard of care, with a sensitivity of 93% at time of relapse.

23. Natera has also collaborated with Aarhus University in Denmark, Imperial College London, University of Leicester, Institute Jules Bordet, Fox Chase Cancer Center, University of California, San Francisco, and Foundation Medicine, Inc with respect to cancer research.

24. The U.S. Food and Drug Administration ("FDA") recognized the importance of Natera's Signatera® and granted it "Breakthrough Device" designation on May 6, 2019. That designation will help accelerate FDA assessment and review of Signatera as an in vitro diagnostic for use in pharmaceutical trials.

25. Signatera's validation has also led Medicare to issue a draft Local Coverage Determination ("LCD") for Signatera in March 2019. In its draft LCD, Medicare determined that "[t]he analytical validity and clinical validity of minimal residual disease testing using cell-free DNA, and Signatera in particular, appears to be well established based on available information for the test." In August 2019, the Palmetto MolDX program, which is run by Medicare

Administrative Contractors, proposed a LCD for use of the "Signatera molecular residual disease (MRD) test in patients with certain forms of colorectal cancer."

26. The Asserted Patents resulted from Natera's years-long research in developing innovative new methods for amplifying and sequencing nucleic acids, including cell-free DNA.

General Background of the Inventions

27. The '814 patent, attached hereto as Exhibit 1, is entitled "Methods for Simultaneous Amplification of Target Loci" and was issued by the United States Patent and Trademark Office ("USPTO") on January 21, 2020. Natera owns the '814 patent, including the right to enforce it and seek damages for infringement.

28. The '814 patent claims methods for simultaneously amplifying multiple nucleic acid regions of interest in a single reaction volume. The claimed methods use polymerase chain reaction ("PCR") to amplify and high-throughput sequencing ("HTS") to sequence the nucleic acids. Independent claim 1 of the '814 patent recites:

> A method for amplifying and sequencing DNA, comprising:
>
> ligating adaptors to cell-free DNA isolated from a biological sample, wherein the adaptors each comprises a universal priming site;
>
> performing a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume;
>
> performing a second, nested PCR to simultaneously amplify the at least 10 target loci using the universal primer and at least 10 inner target-specific primers in a single reaction volume, wherein at least one of the primers comprises a sequencing tag;
>
> performing high-throughput sequencing to sequence the amplified DNA comprising the target loci.

29. The '172 patent, attached hereto as Exhibit 2, is entitled "Methods for Simultaneous Amplification of Target Loci" and was issued by the United States Patent and Trademark Office

("USPTO") on February 11, 2020. Natera owns the '172 patent, including the right to enforce it and seek damages for infringement.

30. The '172 patent claims methods for simultaneously amplifying multiple nucleic acid regions of interest in a single reaction volume. The claimed methods use polymerase chain reaction ("PCR") to amplify and high-throughput sequencing ("HTS") to sequence the nucleic acids. Independent claim 1 of the '172 patent recites:

> A method for amplifying and sequencing DNA, comprising:
>
> isolating cell-free DNA from a biological sample and tagging the isolated cell-free DNA, wherein each tagged DNA molecule comprises a molecular barcode;
>
> performing a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume;
>
> performing a second, nested PCR to simultaneously amplify the at least 10 target loci using the universal primer and at least 10 inner target-specific primers in a single reaction volume;
>
> performing high-throughput sequencing to sequence the amplified DNA comprising the target loci.

31. The '482 patent, attached hereto as Exhibit 3, is entitled "Methods for Non-Invasive Prenatal Paternity Testing" and was issued by the United States Patent and Trademark Office ("USPTO") on March 17, 2020. Natera owns the '482 patent, including the right to enforce it and seek damages for infringement.

32. The '482 patent claims methods for simultaneous nested amplification of multiple nucleic acid regions of interest in a single reaction volume. Independent claim 1 of the '482 patent recites:

> A method for nested PCR amplification, comprising:
>
> isolating cell-free DNA from a biological sample and ligating adaptors to the isolated cell-free DNA, wherein the adaptors each comprise a universal priming site, wherein (i) the adaptors each comprise a molecular barcode and/or (ii) at least one of the primers comprises a sequencing tag;

> performing a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a first reaction volume; and
>
> performing a second, nested PCR to simultaneously amplify the at least 10 target loci using the universal primer and at least 10 inner target-specific primers in a second reaction volume to obtain amplified DNA, wherein primer binding sites of the inner target-specific primers of the second PCR are internal to primer binding sites of the target-specific primers of the first PCR, wherein at least 80% of the amplified DNA maps to the target loci.

33. The ’708 patent, attached hereto as Exhibit 4, is entitled “Methods for Simultaneous Amplifications of Target Loci” and was issued by the United States Patent and Trademark Office (“USPTO”) on March 24, 2020. Natera owns the ’708 patent, including the right to enforce it and seek damages for infringement.

34. The ’708 patent claims methods for simultaneously amplifying multiple nucleic acid regions of interest in a reaction mixture. The claimed methods amplify the nucleic acids under particular reaction conditions and sequence the nucleic acids. Independent claim 1 of the ’708 patent recites:

> A method of amplifying target loci in a nucleic acid sample, the method comprising:
>
> contacting the nucleic acid sample comprising target loci with a library of at least 2 primers that simultaneously hybridize to at least 2 of the target loci to produce a reaction mixture;
>
> subjecting the reaction mixture to primer extension reaction conditions to produce amplified products comprising target amplicons; wherein the annealing temperature for the reaction conditions is greater than a melting temperature of the at least 2 primers, wherein the length of the annealing step of the reaction conditions is greater than 3 minutes, and wherein the at least 2 of the target loci are simultaneously amplified; and sequencing the amplified products.

The '814 Patent Is Not Directed To A Natural Phenomenon And Its Steps Were Not Routine Or Conventional

35. The claims of the '814 patent are not directed to a natural law or natural phenomenon. Rather, they are directed to amplifying and sequencing DNA in a sample using synthetic primers and amplification products to provide a novel and innovative solution to problems peculiar to the particular problem of amplifying and sequencing small amounts of cell-free DNA from tumor cells in a biological sample. Moreover, the claims of the '814 patent cover methods of preparation. Analogous claims were held not be directed to a natural law or phenomenon in the recent Federal Circuit decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 2019-1419, 2020 WL 1264002 (Fed. Cir. Mar. 17, 2020).

36. The '814 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to amplify and use HTS to sequence nucleic acids obtained from circulating tumor DNA with the use of a universal primer and a sequencing tag in the context of the invention.

37. In allowing '814 patent claims, the USPTO examiner found the claims to be non-routine and non-conventional, and stated:

> [T]he claims have been carefully reviewed and the claimed invention distinguishes over the art because the closest references in the art do not teach, or render obvious, each aspect of the claimed invention. The closest art, Chowdary et al. (US PgPub 20080305473; December 2008) teaches a method of nested multiplex amplification of circulating tumor cells, but there are significant differences between the teachings of Chowdary and the claimed method steps. Chowdary focuses on amplification of nucleic acids obtained from circulating tumor cells and not on circulating nucleic acids, Chowdary does not teach any sequencing steps, does not incorporate a universal or common primer and does not include a sequencing tag. Further, Chowdary specifically teaches away from modification to focus on circulating nucleic

> acids, Chowdary specifically includes a step of isolation of circulating tumor cells (CTCs) followed by extraction of nucleic acids and amplification of the nucleic acid, steps which would exclude modifying Chowdary to arrive at the method steps as claimed.
>
> Further, an additional reference, Gocke et al. (US Patent 6156504; December 2000) teaches analysis of circulating nucleic acids that include semi-nested amplification, and a general mention of multiplex amplification. However, there are also significant differences between Gocke and the claimed method steps because Gocke only mentions sequencing in a prophetic example, does not teach or suggest the inclusion of universal or common primers or the inclusion of sequencing tags.
>
> Therefore, since neither Chowdary nor Gocke teach or suggest each and every step of the method, as claimed, the claims are novel and non-obvious over the prior art.

38. None of the references U.S. Patent App. Pub. No. 2010/0120038 ("Mir"), Diego Spertini, *Screening of Transgenic Plants by Amplification of Unknown Genomic DNA Flanking T-DNA*, 27 BioTechniques 308 (1999) ("Spertini"), and U.S. Patent App. No. 2007/0031857 ("Makarov"), either alone or in combination with each other, anticipate or render obvious any of the claims of the '814 patent.

The '172 Patent Is Not Directed To A Natural Phenomenon And Its Steps Were Not Routine Or Conventional

39. The claims of the '172 patent are not directed to a natural law or natural phenomenon. Rather, they are directed to amplifying and sequencing DNA in a sample using synthetic primers and amplification products to provide a novel and innovative solution to problems peculiar to the particular problem of amplifying and sequencing small amounts of cell-free DNA from tumor cells in a biological sample. Moreover, the claims of the '172 patent cover methods of preparation. Analogous claims were held not be directed to a natural law or phenomenon in the recent Federal Circuit decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 2019-1419, 2020 WL 1264002 (Fed. Cir. Mar. 17, 2020).

40. The '172 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to amplify and use HTS to sequence nucleic acids obtained from cell-free DNA with the use of a universal primer and a molecular barcode in the context of the invention.

41. In allowing '172 patent claims, the USPTO examiner found the claims to be non-routine and non-conventional, and stated:

> [T]he claims have been carefully searched and the claimed invention distinguishes over the art. The closest references in the art do not teach, or render obvious, each aspect of the claimed invention. The closest art, Chowdary et al. (US PgPub 20080305473; December 2008) teaches a method of nested multiplex amplification, of circulating tumor cells. However, there are significant differences between the teachings of Chowdary and the claimed invention, as Chowdary focuses on amplification of nucleic acids obtained from circulating tumor cells and not on circulating nucleic acids, Chowdary does not teaching sequencing steps and does not incorporate a universal or otherwise common primer within the amplification. Further, Chowdary specifically teaches away from modification to analyze circulating nucleic acids, as the method includes specific isolation of circulating tumor cells (CTCs) followed by extraction of nucleic acids and amplification of the nucleic acid.
>
> Further, an additional reference, Gocke et al. (US Patent 6156504; December 2000) teaches analysis of circulating nucleic acids that include semi-nested amplification, and a general mention of multiplex amplification. However, there are also significant differences between Gocke and the claimed method, as Gocke only mentions sequencing in a prophetic example, and does not teach or suggest either universal or common primers for the amplification steps.
>
> Therefore, as both Chowdary and Gocke do not teach or suggest each and every step of the method, as claimed, the claims are novel and non-obvious over the prior art.

The '482 Patent Is Not Directed To A Natural Phenomenon And Its Steps Were Not Routine Or Conventional

42. The claims of the '482 patent are not directed to a natural law or natural phenomenon. Rather, they are directed to amplifying DNA in a sample using synthetic primers and amplification products to provide a novel and innovative solution to problems peculiar to the particular problem of amplifying small amounts of cell-free DNA from tumor cells in a biological sample. Moreover, the claims of the '482 patent cover methods of preparation. Analogous claims were held not be directed to a natural law or phenomenon in the recent Federal Circuit decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 2019-1419, 2020 WL 1264002 (Fed. Cir. Mar. 17, 2020).

43. The '482 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to use nested PCR amplification to amplify nucleic acids obtained from circulating tumor DNA with the use of a universal primer, and wherein at least 80% of the amplified DNA maps to the target loci, in the context of the invention.

44. In allowing '482 patent claims, the USPTO examiner found the claims to be non-routine and non-conventional, and stated:

> The claims are free of the analogous art at least because the art does not teach the recited 'nested PCR' following the recited 'first PCR' of 'cell-free DNA' with the recited amplification targeting.

The '708 Patent Is Not Directed To A Natural Phenomenon And Its Steps Were Not Routine Or Conventional

45. The claims of the '708 patent are not directed to a natural law or natural phenomenon. Rather, they are directed to amplifying and sequencing nucleic acid samples using synthetic primers and amplification products to provide a novel and innovative solution to problems

peculiar to the particular problem of amplifying and sequencing small amounts of nucleic acid samples. Moreover, the claims of the '708 patent cover methods of preparation. Analogous claims were held not be directed to a natural law or phenomenon in the recent Federal Circuit decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 2019-1419, 2020 WL 1264002 (Fed. Cir. Mar. 17, 2020).

46. The '708 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to amplify and sequence nucleic acids obtained from nucleic acid samples with the use of multiple primers that simultaneously hybridize, and wherein the melting temperature of at least two of the pairs of primers is less than the annealing temperature used, in the context of the invention.

47. In allowing '708 patent claims, the USPTO examiner found the claims to be non-routine and non-conventional, and stated:

> Applicant's arguments regarding Spier and Ishii are persuasive regarding the claimed feature of selecting an annealing temperature greater than the melting temperature of at least two of the pairs of primers. Further, Applicant's arguments regarding the significant advantages provided by the selection of the higher annealing temperature in reduction of primer dimer formation were particularly persuasive as evidence of the non-obviousness of the claimed invention.
>
> The prior art does not teach or suggest each of the features of the claimed method including the selection of an annealing temperature higher than the melting temperature of the primers, the selection of a long annealing time and sequencing of the amplification products. Therefore the claims are novel and non-obvious over the prior art.

ARCHER'S INFRINGING ACTIVITIES

48. Archer sells products using its AMP technology on nucleic acids, including tumor DNA. One such product is LiquidPlex, which applies AMP to ctDNA to detect and monitor

genes commonly associated with cancers. Another such product is Stratafide, which is a pan-solid tumor test designed to identify actionable genomic alterations in tissue or blood samples. A third such product is PCM, a bespoke product that uses AMP for cancer treatment monitoring and recurrence surveillance. A fourth such product is ArcherMET, which uses AMP to detect MET gene alterations, such as exon 14 skipping alterations, in ctDNA. A fifth such product is FusionPlex, which is a targeted sequencing assay that simultaneously detects and identifies fusions and other mutations associated with cancers. A sixth such product is VariantPlex, which is a targeted sequencing assay that simultaneously detects and characterizes single-nucleotide variants, copy number variations, and insertions and deletions associated with cancers.

49. Attached as Exhibit 5 is a preliminary and exemplary claim chart describing Archer's infringement of claim 1 of the '814 patent. Exhibits 9-20 are supporting documents for the Exhibit 5 chart. The claim chart is not intended to limit Natera's right to modify the chart or allege that other activities of Archer infringe the identified claim or any other claims of the '814 patent or any other patents. Archer infringes more than one claim of the '814 patent.

50. Exhibit 5 is hereby incorporated by reference in its entirety. Each claim element in Exhibit 5 that is mapped to Archer's LiquidPlex, Stratafide, PCM, and ArcherMET products, and any other oncology products that use the same technology as the previously mentioned products (collectively, "cfDNA Accused Products") shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each claim element is required.

51. Attached as Exhibit 6 is a preliminary and exemplary claim chart describing Archer's infringement of claim 1 of the '172 patent. Exhibits 9-20 are supporting documents for the Exhibit 6 chart. The claim chart is not intended to limit Natera's right to modify the chart or

allege that other activities of Archer infringe the identified claim or any other claims of the '172 patent or any other patents. Archer infringes more than one claim of the '172 patent.

52. Exhibit 6 is hereby incorporated by reference in its entirety. Each claim element in Exhibit 6 that is mapped to Archer's cfDNA Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each claim element is required.

53. Attached as Exhibit 7 is a preliminary and exemplary claim chart describing Archer's infringement of claim 1 of the '482 patent. Exhibits 9-20 are supporting documents for the Exhibit 7 chart. The claim chart is not intended to limit Natera's right to modify the chart or allege that other activities of Archer infringe the identified claim or any other claims of the '482 patent or any other patents. Archer infringes more than one claim of the '482 patent.

54. Exhibit 7 is hereby incorporated by reference in its entirety. Each claim element in Exhibit 7 that is mapped to Archer's cfDNA Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each claim element is required.

55. Attached as Exhibit 8 is a preliminary and exemplary claim chart describing Archer's infringement of claim 1 of the '708 patent. Exhibits 9-18 and 20-32 are supporting documents for the Exhibit 8 chart. The claim chart is not intended to limit Natera's right to modify the chart or allege that other activities of Archer infringe the identified claim or any other claims of the '708 patent or any other patents. Archer infringes more than one claim of the '708 patent.

56. Exhibit 8 is hereby incorporated by reference in its entirety. Each claim element in Exhibit 8 that is mapped to Archer's Accused Products shall be considered an allegation within

the meaning of the Federal Rules of Civil Procedure and therefore a response to each claim element is required.

57. Archer's AMP process is a method for amplifying and sequencing DNA.

58. Archer's AMP process can include ligation of adaptors to cell-free DNA isolated from a biological sample.

59. Archer's AMP process can include ligation of adaptors that each comprise a universal priming site.

60. Archer's AMP process can include a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume.

61. Archer's AMP process can include a second, nested PCR to simultaneously amplify the at least 10 target loci using the universal primer and at least 10 inner target-specific primers in a single reaction volume.

62. Archer's AMP process can include primers comprising a sequencing tag.

63. Archer's AMP process can include performing HTS to sequence the amplified DNA comprising the target loci.

64. Archer's AMP process can be performed on a biological sample that is a blood, plasma, serum, or urine sample.

65. Archer's AMP process can include subjecting the isolated cell-free DNA to blunting ending, dA-tailing, and adaptor ligation.

66. Archer's AMP process can use an adaptor that includes a molecular barcode.

67. In Archer's AMP process, the second PCR can be a one-sided nested PCR.

68. Archer's AMP process can include multiplex sequencing of amplified DNA of multiple samples in a single sequencing lane.

69. Archer's AMP process can include a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume.

70. Archer's AMP process can include a first PCR that simultaneously amplifies at least 50 target loci using the universal primer and at least 50 target-specific primers in a single reaction volume.

71. Archer's AMP process can include a first PCR that simultaneously amplifies at least 100 target loci using the universal primer and at least 100 target-specific primers in a single reaction volume.

72. Archer's AMP process can include a second PCR that simultaneously amplifies at least 50 target loci using the universal primer and at least 50 target-specific primers in a single reaction volume.

73. Archer's AMP process can include a second PCR that simultaneously amplifies at least 100 target loci using the universal primer and at least 100 target-specific primers in a single reaction volume.

74. In Archer's AMP process, the isolated cell-free DNA can be tagged with 1024-65536 different molecular barcodes.

75. In Archer's AMP process, the concentration of each target-specific primer of the first and/or second PCR can be less than 20 nM.

76. In Archer's AMP process, the concentration of each target-specific primer of the first and/or second PCR can be less than 10 nM.

77. In Archer's AMP process, the length of the annealing step of the first and/or second PCR can be at least 3 minutes.

78. In Archer's AMP process the length of the annealing step of the first and/or second PCR can be at least 5 minutes.

79. In Archer's AMP process, at least 90% of the amplified DNA can be mapped to the target loci.

80. In Archer's AMP process, target loci can include SNP loci.

81. In Archer's AMP process, the cell-free DNA can comprises DNA from mixed origin.

82. In Archer's AMP process, the cell-free DNA can comprise DNA from a tumor.

83. Archer's AMP process can include a second one-sided nested PCR.

84. Archer's AMP process can be a method for nested PCR amplification.

85. In Archer's AMP process, at least 80% of the amplified DNA can be mapped to the target loci.

86. Archer's AMP process can be a method of amplifying target loci in a nucleic acid sample.

87. Archer's AMP process can include contacting the nucleic acid sample comprising target loci with a library of at least 2 primers that simultaneously hybridize to at least 2 of the target loci to produce a reaction mixture.

88. In Archer's AMP process, the reaction mixture can be subjected to primer extension reaction conditions, including an annealing temperature greater than a melting temperature of at least 2 primers and an annealing duration of greater than 3 minutes, to produce amplified products comprising target amplicons.

89. In Archer's AMP process, at least 2 of the target loci can be simultaneously amplified.

90. In Archer's AMP process, the amplified products can be sequenced.

91. In Archer's AMP process, the range of melting temperatures of the primers can be less than 5° C.

92. In Archer's AMP process, at least 10 target loci can be amplified with at least 10 primers.

93. In Archer's AMP process, at least 50 target loci can be amplified with at least 50 primers.

94. In Archer's AMP process, at least 100 target loci can be amplified with at least 100 primers.

95. In Archer's AMP process, at least 90% of the amplified products can be target amplicons.

96. In Archer's AMP process, less than 20% of the amplified products can be primer dimers.

97. Archer's AMP process can include an annealing step that is 5-60 minutes long.

98. Archer began commercially selling and offering to sell LiquidPlex for investigational and research use only on or about September 22, 2016. These sales, offers for sale, and uses do not require FDA medical device approval, and therefore are not solely for uses reasonably related to any such submission.

99. An unnamed product was designated as receiving FDA's Breakthrough Device Designation on or about January 2019. At the time, the only liquid biopsy technology that was publicly disclosed by Archer was the technology underlying its LiquidPlex product. Upon

information and belief, the undisclosed product on or about January 2019 used the same technology as LiquidPlex.

100. Archer has been commercially selling and offering to sell FusionPlex for investigational and research use only. These sales, offers for sale, and uses do not require FDA medical device approval, and therefore are not solely for uses reasonably related to any such submission.

101. Archer has been commercially selling and offering to sell for investigational and research use only VariantPlex. These sales, offers for sale, and uses do not require FDA medical device approval, and therefore are not solely for uses reasonably related to any such submission.

102. Upon information and belief, ArcherMET is manufactured in the United States and then subsequently shipped overseas for commercial sale, offer for sale, and/or use outside the United States (and may also be used, offered for sale, or sold in the United States). For example, ArcherMET was recently approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) and Japan's Pharmaceutical Medical Devices Agency (PMDA). These sales, offers for sale, and uses do not require FDA medical device approval, and therefore Archer has engaged in manufacturing that is not solely for uses reasonably related to any such submission.

103. On December 17, 2019, Archer announced the close of a $55 million Series C financing round, the proceeds of which are intended to be used to support the launch of Stratafide and PCM. In a statement from December 17, 2019, Jason Myers, co-founder and chief executive officer of Archer stated that "[t]he proceeds position ArcherDX to, upon approval, launch STRATAFIDE" and "advance our Personalized Cancer Monitoring platform." This financing round was led by Perceptive Advisors, and joined by other investors including Redmile Group, Soleus Capital, Driehaus Capital Management, ArrowMark Partners, Sands Capital,

Longwood Fund, PBM Capital and its affiliates, and Boulder Ventures. Upon information and belief, Archer received this financing as a result of its infringing use of Natera's patented technology.

104. Archer has commercially sold and offered for sale the infringing technology in Stratafide and PCM. For example, Archer has commercially licensed the technology to Illumina and others. These sales, offers for sale, and licensed uses do not require FDA medical device approval, and therefore Archer has engaged in infringing activities that are not solely for uses reasonably related to any such submission. On January 10, 2019, Archer announced a non-exclusive, multi-year partnership with Illumina. This partnership is intended to broaden access of Archer's products. In the January 10, 2019 announcement, Archer Chief Executive Officer Jason Myers stated that the partnership was expected to accelerate the process of creating broad access to testing, shifting away from a handful of centralized sequencing labs to decentralized testing. Myers further stated that the partnership would allow hospitals and local labs to benefit from a "growing share of the cancer diagnostics and monitoring market." Archer announced on January 10, 2019 that it anticipated that Stratafide would be the first IVD to be marketed under the partnership between Archer and Illumina. Archer also announced that it planned to launch PCM for diagnostic use as part of this commercial partnership. In the January 10, 2019 press release, Dr. Phil Febbo, Chief Medical Officer of Illumina, stated that Archer and Illumina were "pleased to take this next step in [their] commercial partnership to support expanding access to leading-edge genomic cancer management to more patients, in more communities, to improve patient outcomes."

105. Upon information and belief, Stratafide and PCM are being commercially sold or offered for sale for use in clinical trials and research use only basis. These sales, offers for sale,

and licensed uses do not require FDA medical device approval, and therefore Archer has engaged in infringing activities that are not solely for uses reasonably related to any such submission. In particular, Stratafide and PCM has been and will be commercially sold for use in clinical trials sponsored by third-party pharmaceutical companies and that Archer has been and will be financially compensated for such use. Archer has used, and continues to use, infringing technology to compete against Natera in the bidding process of various revenue-generating clinical trials by third-party pharmaceutical companies that involve MRD testing.

106. Upon information and belief, Stratafide and PCM are being used in the on-going Tracking Launch Cancer Evolution Through Treatment (TRACERx) study led by Dr. Charles Swanton and Dr. Christopher Abbosh. On March 28, 2019, Archer announced that it entered into this research collaboration agreement with the University College London ("UCL") and the Francis Crick Institute. This UCL-sponsored study uses infringing AMP technology to expand on findings from an earlier clinical study by developing patient-specific assays to detect low-volume minimal residual disease at high levels of sensitivity.

107. Upon information and belief, the Accused Products manufactured in the United States have been or will be used overseas. These manufacturing activities do not require FDA medical device approval, and therefore Archer has engaged in infringing activities that are not solely for uses reasonably related to any such submission. For example, Archer announced on January 10, 2019 that the partnership between Archer and Illumina expands upon a prior agreement between the two companies to co-market and co-promote FusionPlex in markets outside of the United States. On June 6, 2016, Archer had announced a co-marketing and distribution agreement with Illumina under which Illumina would market and promote FusionPlex "through its global commercial channels" Under the 2016 agreement, Archer would

sell its products in the United States while Illumina would distribute FusionPlex in international markets on a non-exclusive basis. Further, on March 25, 2020, Archer announced that its product ArcherMET was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) and Japan's Pharmaceutical Medical Devices Agency (PMDA).

108. Archer received the FDA's Breakthrough Device Designation for Stratafide on or about January 2019, and Archer intends to sell the product for diagnostic use immediately upon approval. In submitting an application for Stratafide to the FDA, Archer had to describe the product with specificity. In particular, upon information and belief, Archer would have had to describe the specific intended use of the product, the specific primers used, and the specific genetic alterations targeted.

109. Archer received the FDA's Breakthrough Device Designation for PCM on or about January 15, 2020, and Archer intends to sell the product for diagnostic use immediately upon approval. In submitting an application for PCM to the FDA, Archer had to describe the product with specificity. In particular, upon information and belief, Archer would have had to describe the specific intended use of the product, the specific primers used, and the specific genetic alterations targeted.

110. Archer has its own CLIA-certified laboratory that has or will use one or more of the Accused Products.

111. LiquidPlex is sold as a kit or as component parts so that the assay can be performed by others.

112. ArcherMET will be sold as a kit or as component parts so that the assay can be performed by others.

113. Stratafide will be sold as a kit or as component parts so that the assay can be performed by others.

114. PCM will be sold as a kit or as component parts so that the assay can be performed by others.

115. FusionPlex is sold as a kit or as component parts so that the assay can be performed by others.

116. VariantPlex is sold as a kit or as component parts so that the assay can be performed by others.

117. Archer's development of its Accused Products has been aided by access to and use of Natera's innovative research and development.

118. For example, Natera worked with Dr. Charles Swanton at the UCL to validate its Signatera® technology in the TRACERx lung cancer study. The study involves analyzing the intratumor heterogeneity of lung tumors in approximately 850 patients and the tracking its evolution from diagnosis to relapse. Dr. Swanton, in his role as the principal investigator, senior researcher, and author of the study, led the development of bespoke personalized assays to target variants selected after the sequencing of primary tumors. After surgery, patients were followed to track clonal and subclonal evolution of the disease based on ctDNA measurements of blood samples. Over twenty PCR assays were designed and analyzed for each specimen, without splitting plasma samples, so that multiple subclones were tracked simultaneously. Subsequent to that collaboration, Archer announced that it was collaborating with Dr. Swanton on that same study and used similar methodology. A January 14, 2020 Archer press release states that Archer has an "on-going collaboration" with Dr. Swanton, who is now "utilizing ArcherDX's technology … to help achieve" the goals of the TRACERx study.

119. Upon information and belief, Archer was able to develop its Accused Products, including its Stratafide and PCM products, as a direct result of unlawful use of Natera's innovative technology.

120. Archer is a direct competitor of Natera in the market for recurrence monitoring for lung cancer.

121. Archer has knowledge of the '814 patent at least as early as January 27, 2020.

122. Archer has knowledge of the '172 patent at least as early as the date of this first amended complaint.

123. Archer has knowledge of the '482 patent at least as early as the date of this first amended complaint.

124. Archer has knowledge of the '708 patent at least as early as the date of this first amended complaint.

COUNT I
(Infringement of U.S. Patent No. 10,538,814)

125. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

126. Natera is the owner of the '814 patent, which was duly and legally issued by the USPTO on January 21, 2020.

127. Archer has infringed and continues to infringe at least one claim of the '814 patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing within the United States and without authority the tests of the cfDNA Accused Products.

128. Archer has infringed and continues to infringe at least one claim of the '814 patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States the cfDNA Accused Products and instructing end-users through instructional materials, product manuals, and technical materials, disseminating

promotional/marketing materials that describe the workflows and use of those tests, and otherwise instructing end-users to use the cfDNA Accused Products to infringe at least claim of the '814 patent. At least as of the date hereof, Archer sells and distributes the cfDNA Accused Products with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '814 patent, and therefore Archer induces end-users to use the cfDNA Accused Products in methods that directly infringe at least one claim of the '814 patent.

129. Archer has infringed and continues to infringe at least one claim of the '814 patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling the cfDNA Accused Products within the United States for use by end-users in practicing at least one of the claimed methods of the '814 patent. The cfDNA Accused Products each constitutes a material part of the invention of the '814 Patent, and, at least as of the date hereof, Archer knows the cfDNA Accused Products to be especially made or especially adapted for use in infringing the '814 patent. Furthermore, none of the cfDNA Accused Products is a staple article or commodity of commerce suitable for substantial noninfringing use. Archer sells and offers for sale the cfDNA Accused Products with the knowledge and specific intent that its instructions and workflows will cause end-users to use the products to infringe at least one claim of the '814 patent.

130. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

131. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '814 patent.

COUNT II
(Declaratory Judgment of Infringement of U.S. Patent No. 10,538,814)

132. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

133. Archer has sought and received the FDA's Breakthrough Device designation for at least some of the cfDNA Accused Products, including Stratafide and PCM. Natera believes, and on that basis alleges, that Archer intends to engage in the commercial manufacture, use, offer for sale, and sale of the cfDNA Accused Products if and when it receives FDA approval to do so.

134. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of the cfDNA Accused Products has or will infringe one or more claims of the '814 patent.

135. Natera is entitled to a judicial declaration that Archer has infringed or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '814 patent.

136. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

137. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '814 patent.

COUNT III
(Infringement of U.S. Patent No. 10,557,172)

138. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

139. Natera is the owner of the '172 patent, which was duly and legally issued by the USPTO on February 11, 2020.

140. Archer has infringed and continues to infringe at least one claim of the '172 patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing within the United States and without authority the tests of the cfDNA Accused Products.

141. Archer has infringed and continues to infringe at least one claim of the '172 patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States the cfDNA Accused Products and instructing end-users through instructional materials, product manuals, and technical materials, disseminating promotional/marketing materials that describe the workflows and use of those tests, and otherwise instructing end-users to use the cfDNA Accused Products to infringe at least claim of the '172 patent. At least as of the date hereof, Archer sells and distributes the cfDNA Accused Products with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '172 patent, and therefore Archer induces end-users to use the cfDNA Accused Products in methods that directly infringe at least one claim of the '172 patent.

142. Archer has infringed and continues to infringe at least one claim of the '172 patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling the cfDNA Accused Products within the United States for use by end-users in practicing at least one of the claimed methods of the '172 patent. The cfDNA Accused Products each constitutes a material part of the invention of the '172 Patent, and, at least as of the date hereof, Archer knows the cfDNA Accused Products to be especially made or especially adapted for use in infringing the '172 patent. Furthermore, none of the cfDNA Accused Products is a staple article or commodity of commerce suitable for substantial noninfringing use. Archer sells and offers for sale the cfDNA Accused Products with the knowledge and specific intent that its

instructions and workflows will cause end-users to use the products to infringe at least one claim of the '172 patent.

143. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

144. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '172 patent.

COUNT IV
(Declaratory Judgment of Infringement of U.S. Patent No. 10,557,172)

145. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

146. Archer has sought and received the FDA's Breakthrough Device designation for at least some of the cfDNA Accused Products, including Stratafide and PCM. Natera believes, and on that basis alleges, that Archer intends to engage in the commercial manufacture, use, offer for sale, and sale of the cfDNA Accused Products if and when it receives FDA approval to do so.

147. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of the cfDNA Accused Products has or will infringe one or more claims of the '172 patent.

148. Natera is entitled to a judicial declaration that Archer has infringed or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '172 patent.

149. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

150. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '172 patent.

COUNT V
(Infringement of U.S. Patent No. 10,590,482)

151. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

152. Natera is the owner of the '482 patent, which was duly and legally issued by the USPTO on March 17, 2020.

153. Archer has infringed and continues to infringe at least one claim of the '482 patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing within the United States and without authority the tests of the cfDNA Accused Products.

154. Archer has infringed and continues to infringe at least one claim of the ' 482 patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States the cfDNA Accused Products and instructing end-users through instructional materials, product manuals, and technical materials, disseminating promotional/marketing materials that describe the workflows and use of those tests, and otherwise instructing end-users to use the cfDNA Accused Products to infringe at least claim of the ' 482 patent. At least as of the date hereof, Archer sells and distributes the cfDNA Accused Products with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '482 patent, and therefore Archer induces end-users to use the cfDNA Accused Products in methods that directly infringe at least one claim of the '482 patent.

155. Archer has infringed and continues to infringe at least one claim of the '482 patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling the cfDNA Accused Products within the United States for use by end-users in practicing at least one of the claimed methods of the '482 patent. The cfDNA Accused Products each constitutes a material part of the invention of the '482 Patent, and, at least as of the date hereof, Archer knows the cfDNA Accused Products to be especially made or especially adapted for use in infringing the '482 patent. Furthermore, none of the cfDNA Accused Products is a staple article or commodity of commerce suitable for substantial noninfringing use. Archer sells and offers for sale the cfDNA Accused Products with the knowledge and specific intent that its instructions and workflows will cause end-users to use the products to infringe at least one claim of the '482 patent.

156. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

157. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '482 patent.

COUNT VI
(Declaratory Judgment of Infringement of U.S. Patent No. 10,590,482)

158. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

159. Archer has sought and received the FDA's Breakthrough Device designation for at least some of the cfDNA Accused Products, including Stratafide and PCM. Natera believes, and on that basis alleges, that Archer intends to engage in the commercial manufacture, use, offer for sale, and sale of the cfDNA Accused Products if and when it receives FDA approval to do so.

160. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of the cfDNA Accused Products has or will infringe one or more claims of the '482 patent.

161. Natera is entitled to a judicial declaration that Archer has infringed or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '482 patent.

162. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

163. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '482 patent.

COUNT VII
(Infringement of U.S. Patent No. 10,597,708)

164. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

165. Natera is the owner of the '708 patent, which was duly and legally issued by the USPTO on March 24, 2020.

166. Archer has infringed and continues to infringe at least one claim of the '708 patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing within the United States and without authority the tests of the Accused Products.

167. Archer has infringed and continues to infringe at least one claim of the ' 708 patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States the Accused Products and instructing end-users through

instructional materials, product manuals, and technical materials, disseminating promotional/marketing materials that describe the workflows and use of those tests, and otherwise instructing end-users to use the Accused Products to infringe at least claim of the ' 708 patent. At least as of the date hereof, Archer sells and distributes the Accused Products with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '708 patent, and therefore Archer induces end-users to use the Accused Products in methods that directly infringe at least one claim of the '708 patent.

168. Archer has infringed and continues to infringe at least one claim of the '708 patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling the Accused Products within the United States for use by end-users in practicing at least one of the claimed methods of the '708 patent. The Accused Products each constitute a material part of the invention of the '708 Patent, and, at least as of the date hereof, Archer knows the Accused Products to be especially made or especially adapted for use in infringing the '708 patent. Furthermore, none of the Accused Products is a staple article or commodity of commerce suitable for substantial noninfringing use. Archer sells and offers for sale the Accused Products with the knowledge and specific intent that its instructions and workflows will cause end-users to use the products to infringe at least one claim of the '708 patent.

169. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

170. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '708 patent.

COUNT VIII
(Declaratory Judgment of Infringement of U.S. Patent No. 10,597,708)

171. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

172. Archer has sought and received the FDA's Breakthrough Device designation for at least some of the Accused Products, including Stratafide and PCM. Natera believes, and on that basis alleges, that Archer intends to engage in the commercial manufacture, use, offer for sale, and sale of the Accused Products if and when it receives FDA approval to do so.

173. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of the Accused Products has or will infringe one or more claims of the '708 patent.

174. Natera is entitled to a judicial declaration that Archer has infringed or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '708 patent.

175. Archer's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Archer's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

176. Moreover, Archer's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Archer is enjoined from any and all activities that would infringe the claims of the '708 patent.

PRAYER FOR RELIEF

WHEREFORE, Natera prays for a judgment in its favor and against Archer and respectfully request the following relief:

A. A judgment that Archer directly infringes, induces infringement, and contributorily infringes the Asserted Patents.

B. An order enjoining Archer and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from further infringement of the Asserted Patents.

C. Damages or other monetary relief, including, but not limited to, costs and pre and post-judgment interest, to Natera;

D. A determination that this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys' fees and costs to Natera in this action;

E. Costs and expenses in this action;

F. An order awarding Natera any such other relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Natera hereby demands a jury trial as to all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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April 15, 2020

CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 15, 2020 upon the following in the manner indicated:

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